PFN – Proximal Femoral Nail. Standard PFN and long PFN.

Surgical Technique
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<td>Drill Bit Ø 4.0 mm, length 250 mm, 3-flute, for Quick Coupling</td>
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<td>314.260</td>
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357.590 Measuring Device
357.008 Reverse Awl for PFN
351.050 Tissue Protector
399.505 Hammer, synthetic
311.720 Tap Ø 6.5 mm, cannulated, calibrated, for Hip Pin
357.048 Wrench for Femoral Neck Screw, complete, with Compression Device (consisting of 357.050/357.051/357.052)*
357.791 Depth Gauge for Locking Bolts
319.460 Cleaning Stylet Ø 2.8 mm
357.009 Cleaning Stylet Ø 2.8 mm, length 450 mm
357.071 Hammer Guide, for No. 357.026
357.026 Slotted Hammer 400g, detachable
321.170 Pin Wrench Ø 4.5 mm
357.073 Extraction Holding Sleeve for Hip Pin

*Alternative to no. 357.053
Image intensifier control

This description alone does not provide sufficient background for direct use of DePuy Synthes products. Instruction by a surgeon experienced in handling these products is highly recommended.

Processing, Reprocessing, Care and Maintenance

For general guidelines, function control and dismantling of multi-part instruments, as well as processing guidelines for implants, please contact your local sales representative or refer to:

http://emea.depuysynthes.com/hcp/reprocessing-care-maintenance

For general information about reprocessing, care and maintenance of Synthes reusable devices, instrument trays and cases, as well as processing of Synthes non-sterile implants, please consult the Important Information leaflet (SE_023827) or refer to:

http://emea.depuysynthes.com/hcp/reprocessing-care-maintenance
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Indications/Contraindications

### Standard PFN

**Indications**
- Pertrochanteric fractures
- Intertrochanteric fractures
- High subtrochanteric fractures

**Contraindications**
- Low subtrochanteric fractures
- Femoral shaft fractures
- Isolated or combined medial femoral neck fractures

### Long PFN

**Indications**
- Low and extended subtrochanteric fractures
- Ipsilateral trochanteric fractures
- Combination of fractures (trochanteric area/shaft)
- Pathological fractures

**Contraindications**
- Isolated or combined medial femoral neck fractures

**Note:** ASLS, the Angular Stable Locking System, is indicated in cases where increased stability is needed in fractures closer to the metaphyseal area or in poor quality bone. For more details regarding the intramedullary fixator principle, please consult the ASLS surgical technique (DSEM/TRM/0115/0284) and concept flyer (036.001.017).
Implants for Standard PFN

- End Cap
- Proximal diameter 17.0 mm
- Self-tapping 6.5 mm Hip Pin
  - Lengths 55–100 mm (<5 mm>)
  - For rotational stability
  - Featuring insertion safety stop
- CCD angle 125°/130°/135°
- Self-tapping 11.0 mm Femoral Neck Screw
  - Lengths 80–120 mm (<5 mm>)
  - Featuring insertion safety stop
- Anatomical 6° ML angle
- Distal diameters of 10, 11, and 12 mm enable unreamed insertion
- 4.9 mm Locking Bolt
  - Lengths 26–52 mm (<2 mm>)
  - A choice of static or dynamic interlocking
    (dynamization: 5 mm)
- Flexible distal nail end (length: 58 mm)
- The PFN is available in titanium alloy
  *(TAN) and stainless steel (SSt)
- Total length: 240 mm

* Ti-6Al-7Nb
Quick Steps for Standard PFN

Preparation

A Patient positioning

Approx. 10–15°

Insertion of guide wires for femur opening

A Insertion of guide wires for femoral neck screw and hip pin

Subchondral position

Position guide wires

Approx. 15–20 mm shorter
B Preoperative planning

- **Insertion of Proximal Femoral Nail**
  - Insertion point
  - Image intensifier control (laterally)

C Insertion point

- Approx. 15–20 mm shorter
- Subchondral position

B Open femur

- Image intensifier control (AP)
  - Cortex
  - Nail diameter

C Insertion of Proximal Femoral Nail

- Approx. 15–20 mm shorter
Quick Steps for Standard PFN

A Measure length of hip pin

Insertion of hip pin

A Measure length of femoral neck screw

Insertion of femoral neck screw

A Drill hole for distal locking

Insertion of Locking Bolt and End Cap
B Drill hole for hip pin

C Insertion of hip pin

B Drill hole for femoral neck screw

C Insertion of femoral neck screw

B Insertion of Locking Bolt

C Insertion of End Cap
Patient positioning
Position patient supine on an extension table or a radio-lucent operating table. Position the C-arm of the image intensifier in such a way that it can visualize the proximal femur exactly in the lateral and AP planes. For unimpeded access to the medullary cavity, abduct the upper part of the body by about 10–15° to the contralateral side (or adduct the affected leg by 10–15°).

Determine CCD angle
Take an AP X-ray of the unaffected side preoperatively. Determine the CCD angle using a goniometer or the preoperative planning template (no. 036.588).

Standard PFN is available in 125°/130°/135°.

Reduce fracture
If possible, carry out closed reduction of the fracture under image intensifier control.

Exact reduction and secure fixation of the patient to the operating table are essential for easy handling and a good surgical result.

Precautions:
- Instruments and screws may have sharp edges or moving joints that may pinch or tear user’s glove or skin.
- Handle devices with care and dispose worn bone cutting instruments in an approved sharps container.
Determine nail diameter
Determine the distal nail diameter by placing the AO/ASIF planning template (no. 036.588) over the isthmus on an AP X-ray.

Alternative: Under image intensifier control, place the Radiographic Ruler (357.590) on the femur and position the square marking over the isthmus. If the transition to the cortex is still visible to the left and right of the marking, the corresponding nail diameter may be used.

Note: When selecting the nail size, consider canal diameter, fracture pattern, patient anatomy and post-operative protocol.

Approach
Palpate the greater trochanter.
Make a 5 cm incision approximately 5 to 8 cm proximal from the tip of the greater trochanter. Make a parallel incision in the fasciae of the gluteus medius and split the gluteus medius in line with the fibres.
1

**Determine nail insertion point and insert Guide Wire**

In the AP view, the nail insertion point is normally found on the tip or slightly lateral to the tip of the greater trochanter in the curved extension of the medullary cavity. The medio-lateral angle of the implant amounts to 6°. This means that the 2.8 mm Guide Wire (357.039) must be inserted laterally at an angle of 6° to the shaft. The guide wire can be inserted either manually with the Universal Chuck with T-Handle (393.100) or with the Compact Air Drive II and the Quick Coupling for Kirschner Wires.

In lateral view, place the guide wire in the centre of the medullary cavity to a depth of about 15 cm.

Percutaneous technique: Insert guide wire through the Protection Sleeve 20.0/17.0 (357.001) and the Drill Sleeve 17.0/2.8 (357.002). Then remove the drill sleeve 17.0/2.8.

**Note:** A correctly selected insertion point and angle are essential for a good surgical result. Check the correct position of the guide wire with the aid of x-rays and by positioning a nail anteriorly on the femur.

---

2

**Opening of the femur**

Guide the cannulated 17.0 mm Drill Bit (357.005) over the guide wire through the protection sleeve 20.0/17.0 and ream manually with the Universal Chuck with T-Handle (393.100) as far as the stop on the protection sleeve. Remove protection sleeve and guide wire.

**Precautions:**

- Dispose of the guide wires, do not reuse them.
- Particularly careful drilling is required with unstable multi-fragment fractures. Specifically, avoid varus displacement of the medial fragment by making sure that the hole is drilled both in the medial fragment and the lateral part of the femur.
Option: opening with Reverse Awl
Open the femur or enlarge the entry point with the Reverse Awl (357.008). Use the Tissue Protector (351.050) to spare soft tissues. Drive the awl over the guide wire into the femur until the marking on the awl shaft is level with the trochanter tip.

3 Assemble instruments
Guide the Connecting Screw (357.021) through the Insertion Handle (357.012) and secure the nail tightly to the insertion handle using the Hexagonal Wrench (357.023). The nail diameter has already been determined during preparations for surgery. Ensure that the connection is tight to avoid deviations when inserting the screws through the aiming arm. Do not attach the aiming arm yet.
4
Insertion of Standard PFN

Carefully insert the nail manually as far as possible into the femoral opening. Slight twisting hand movements help insertion. If the nail cannot be inserted, select a smaller size nail diameter.

Insertion can be supported by light blows with the synthetic Hammer (399.505) on the mounted protection shield of the insertion handle.

Precautions:
- If the medullary canal is too narrow, it should be reamed to at least $\Omega 10\,\text{mm}$.
- Make sure that the nail is tightly screwed to the insertion handle before inserting the nail.
- Tap gently on the insertion handle. The use of excessive force will result in loss of reduction or bone fracture. Apply taps only to the protection plate.
- An excessively cranial or caudal nail position will result in incorrect placement of the screws and should therefore be avoided at all.

5
Insertion of femoral neck screw and hip pin

Insert these screws using the colour-coded drill sleeve systems consisting of protection sleeve, drill sleeve and trocar.

Tightly secure the appropriate Aiming Arm (357.015/125°, 357.016/130°, 357.017/135°) to the insertion handle.

The position of the nail can be verified by placing a guide wire on the surface of the insertion handle. The position of the end of the nail can be checked by inserting a wire through the insertion handle.

To ensure the correct anteversion of the implant, an additional guide wire can be inserted ventral to the femoral neck into the femoral head.
6
Insertion of guide wire for femoral neck screw

Make a stab incision and insert the pink Drill Sleeve System (357.031/357.032/357.033) through the aiming arm to the bone. Mark the femur and remove the trocar. Insert a new 2.8 mm Guide Wire (357.039) through the drill sleeve, check direction and position under image intensifier in AP and lateral views. Choose a position in the caudal area of the femoral head so that both proximal screws can be inserted. Insert the guide wire 5 mm deeper into the femoral head than the planned femoral head screw. The final position of the guide wire should be in the lower half of the femoral neck. In lateral view, the wire should be positioned in the centre of the femoral neck.

Note: If the nail has to be repositioned, remove guide wire, protection sleeve and drill sleeve. The nail can now be repositioned by rotation, deeper insertion or partial retraction. Then reinsert the drill sleeve system and guide wire.

Precaution: Make sure the handle is not moved before inserting the hip pin guide wire. Drilling over a bent guide wire can result in drill breakage or damaging of the nail itself.

7
Insertion of guide wire for hip pin

Insert the blue Drill Sleeve System (357.036 NG/357.037 NG/357.038 NG) through the blue drill hole on the aiming arm to the bone. Then remove the trocar and insert a second, new 2.8 mm guide wire through the drill sleeve into the bone. The tip of the guide wire should be positioned at least 20 mm medial of the fracture line and 5 mm deeper than the planned hip pin, but approximately 15–20 mm less deep than the planned femoral neck screw.

Note: Verify that the guide wires are parallel in both planes and that their tips form a horizontal line on the AP view.

Precaution: The use of a hip pin is essential to avoid rotation.

Note: As only the femoral neck screw has a load-bearing function, the hip pin should always be 15–20 mm shorter than the femoral neck screw (as shown in the drawing).
8  
**Measure length of hip pin**

It is recommended to start with the insertion of the hip pin to prevent possible rotation of the medial fragment when inserting the femoral neck screw.

Remove the drill sleeve 6.5/2.8. Guide the Direct Measuring Device (357.042) through the protection sleeve 8.0/6.5 to the bone and determine the length of the required hip pin. The length of this pin is indicated on the measuring device and calculated to end 5 mm before the tip of the guide wire.

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9  
**Drill hole for hip pin**

Advance the cannulated 6.5 mm Drill Bit (357.047) over the 2.8 mm guide wire. Drill to the stop (maximum drilling depth: 45 mm). As the tip of the hip pin is self-tapping, usually no further drilling and tapping is needed.
10
Procedure in hard bone

In hard or young bone, further drilling and tapping with the cannulated 6.5 mm Tap (311.720) is recommended up to the length of the hip pin previously measured.

11
Insertion of hip pin

Use the cannulated Hexagonal Screwdriver (357.055) to insert the selected hip pin over the guide wire to the stop. Remove and discard the 2.8 mm guide wire of the hip pin.

Precaution: Do not insert the hip pin with undue force. Ensure that the lateral end of the hip pin clearly protrudes from the lateral cortex. Check under image intensification that hip pin is not inserted too far.
12

Measure length of femoral neck screw

Remove the pink Drill Sleeve 11.0/2.8 (357.032). Guide the Direct Measuring Device (357.042) over the second 2.8 mm guide wire through the pink protection sleeve 14.0/11.0 until it touches bone, and determine the length of the required femoral neck screw. The correct screw length is indicated on the measuring device and calculated to end approx. 5 mm before the tip of the guide wire. Now set the measured length on the 11.0 mm Reamer (357.045) by securing the Fixation Sleeve (357.046) in the appropriate position. The correct length is indicated on the side of the fixation sleeve facing the reamer tip.

13

Drill hole for femoral neck screw

Advance the 11.0 mm reamer over the 2.8 mm guide wire. Drill to the stop. The fixation sleeve prevents further drilling. Tapping is not required due to the self-tapping tip of the femoral neck screw.

Precautions:
- If the guide wire has been bent slightly during insertion, the reamer can be guided over it using careful forward and backward movements.
- If the guide wire has been bent to a greater extent, it should be reinserted or replaced by a new one. However, in some cases it is possible to cautiously complete reaming without a guide wire.
14
Insertion of femoral neck screw

Assemble the Wrench for Femoral Neck Screw (357.053 consisting of: 357.054/357.051) and secure it tightly to the selected femoral neck screw. Insert the femoral neck screw over the 2.8 mm guide wire to the stop. Remove the wrench for the femoral neck screw, if necessary using the Hexagonal Wrench (357.023). Remove and discard the 2.8 mm guide wire of the femoral neck screw. Finally, remove both protection sleeves from the aiming arm. Check under image intensification that the femoral neck screw protrudes slightly over the lateral cortex.

Option: Wrench for femoral neck screws with compression device

Assemble the Wrench for Femoral Neck Screw (357.048 consisting of: 357.050/357.051/357.052) and secure it tightly to the selected femoral neck screw. The Compression Nut (357.052) must be completely unscrewed in the lateral direction. Insert the femoral neck screw over the 2.8 mm guide wire to the stop. If required, use the Compression Nut (357.052) to compress the fracture with the femoral neck screw. This should be performed with great care to prevent the screw from tearing out. Do not compress in osteoporotic bone.
15

Drill hole for distal locking

Distal locking is usually performed with a single locking bolt. For static interlocking Use the cranial locking hole only for static interlocking, and the caudal locking hole for dynamic interlocking. Subtrochanteric fractures may be double-locked. Postoperative removal of the static locking bolt allows secondary dynamization.

Make a stab incision and insert the green Drill Sleeve System (357.061/357.063/357.065) through the locking hole selected in the aiming arm to the bone.

Remove the green 4.0 mm Trocar (357.065) and drill through both cortices using the 4.0 mm Drill Bit (357.068). Read off the length of the required locking bolt directly from the drill marking. Ensure that the drill sleeve 8.0/4.0 has good bone contact.

Precautions:

– Before distal locking, ensure that no diastasis has occurred intraoperatively. Healing may be delayed if the distal locking bolts are secured despite the presence of diastasis.
– Ensure that all connections between the nail, insertion handle and aiming arm are still secure, otherwise the nail itself may be damaged during drilling of the distal locking holes.

Alternative length measuring

Remove the drill sleeve 8.0/4.0 and determine the bolt length with the Depth Gauge for Locking Bolts (357.791). Add 2 to 4 mm to the reading to ensure that the thread engages the far cortex.
16
Insertion of locking bolt

Insert the locking bolt through the protection sleeve using the large Hexagonal Screwdriver (314.260). Remove the protection sleeve and the aiming arm. Then remove the insertion handle using the Hexagonal Wrench (357.023).

17
Insertion of End Cap

Align the end cap with the nail axis using the hexagonal screwdriver in order to prevent tilting. Screw the end cap completely onto the nail until its collar touches the proximal end of the nail. In order to avoid losing the end cap and to facilitate insertion, the end cap can also be inserted through the Protection Sleeve 20.0/17.0 (357.001).
Implants for long PFN

- End Cap
- Proximal diameter 17.0 mm
- Self-tapping 6.5 mm Hip Pin
  - Lengths 55–100 mm (<5 mm)
  - For rotational stability
  - Featuring insertion safety stop
- Self-tapping 11.0 mm Femoral Neck Screw
  - Lengths 80–120 mm (<5 mm)
  - Featuring insertion safety stop
- CCD angle 125°, 130°
- Anatomical 10° anteversion
- Two different anatomically adapted nail designs for left or right leg
- Anatomical 6° ML angle
- Anatomical 1.5m radius (antecurvature)
- Distal diameters of 10.0 mm
- Cannulated nail
- Total length: 340, 380, and 420 mm

- Distal 4.9 mm Locking Bolt
  - Lengths 26–100 mm (<2 mm) from 26 to 60 mm,
    <4 mm> from 60 to 80 mm, <5 mm> from 80 to 100 mm
  - A choice of static or dynamic interlocking
    (dynamization: 10 mm)

The long PFN is available in titanium alloy and stainless steel. Grooves in stainless steel nails ensure flexibility of the long PFN similar to a 12 mm Solid Femoral Nail (UFN) in titanium alloy (with grooves).
Detailed surgical technique
This surgical technique is based on the PFN standard surgical technique. In order to follow the correct procedure, please refer to the respective steps in the standard technique. This part only shows the steps regarding insertion and distal interlocking of the long PFN which differ from the standard technique.

Usually, the 130° nail is suitable for most indications. In some cases, however, the use of a 125° nail may be indicated.

Patient positioning
Please refer to the PFN standard surgical technique.

Determine CCD angle
Please refer to the PFN standard surgical technique.

Reduce fracture
Please refer to the PFN standard surgical technique. However, the special conditions of the very different fracture types have to be considered.

Determine nail length
Position the image intensifier for an AP view of the proximal femur (1). Use long forceps to hold the Measuring Device (357.590) alongside the lateral aspect of the thigh parallel to and at the same level as the femur. Adjust the C-arm so the beam is centred between the femur and measuring device; this will reduce magnification errors. Adjust the device until the top is level with the tip of the greater trochanter. Mark the skin at the top of the measuring device. Move the image intensifier to the distal femur (2), place the proximal end of the measuring device at the skin mark, and take an AP image of the distal femur. Verify fracture reduction. Read nail length directly from the measuring device image, selecting the measurement that is at or just proximal to the physeal scar, or at the chosen insertion depth. Consider the nail range of 340, 380, and 420 mm.
Surgical Technique for long PFN

Approach
Please refer to the PFN standard surgical technique.

1 Determine nail insertion point and insert guide wire

In the AP view, the nail insertion point is normally found on the tip or slightly lateral to the tip of the greater trochanter in the curved extension of the medullary cavity. The mediolateral angle of the implant amounts to 6°. This means that the 2.8 mm Guide Wire (357.039) must be inserted laterally at an angle of 6° to the shaft. The guide wire can be inserted either manually with the Universal Chuck with T-Handle (393.100) or with the Compact Air Drive II and with the Quick Coupling for Kirschner Wires.

In the lateral view, place the guide wire in the centre of the medullary cavity.

2 Open femur

Guide the cannulated 17.0 mm Drill Bit (357.005) through the Protection Sleeve 20.0/17.0 (357.001) over the guide wire, and ream manually with the Universal Chuck with T-Handle (393.100) as far as the stop on the protection sleeve (see standard PFN, page 12).

Remove protection sleeve and guide wire. Do not reuse the guide wire.

Precaution: Particularly careful drilling is required with unstable multifragment fractures. Specifically, avoid varus displacement of the medial fragment by making sure that the hole is drilled both in the medial fragment and the lateral part of the femur.

Optional opening with the reverse awl: see PFN standard surgical technique, page 13).
Directives for medullary reaming (optional technique)*

Reduction
Insert the reduction system, consisting of a T-handle (351.150), a flexible Shaft (352.040), a Reaming Rod and a Reduction Head (352.050 or 352.055) into the medullary canal, and reduce the fragments under image-intensifier control.
After reduction, remove the reduction system, and leave the reaming rod in the medullary cavity.

Medullary reaming
The reaming rod is already in the medullary canal, if the reduction has been achieved by means of the reduction system.
For initial reaming, the flexible shaft is usually equipped with the 8.5 mm Reamer Head (352.085).
Use the highest speed and slight but uniform force to advance the reamer head in the medullary canal. Move the flexible shaft forwards and backwards to remove the bone chips from the reamer head. This prevents jamming of the reamer head in the medullary canal.
Use sideways cutting reamer heads for the subsequent reaming steps.
Ream to the desired diameting in 0.5 mm increments.
Remove the reaming rod before locking the intramedullary nail.

* For further details, see the SynReam surgical technique (DSEM/TRM/0614/0103)

4
Assemble instruments
Please refer to the PFN standard surgical technique.

Note: Choose the appropriate nail for the left or right leg.
5
Insert long Proximal Femoral Nail

If no reaming has been performed, the guide rod may help nail insertion, but is usually not necessary. Carefully insert the nail manually (be it over the guide rod or not) as far as possible into the femoral opening. Slight twisting hand movements help insertion. If necessary, insertion can be supported by light hammering blows. Therefore, insert the Thread Gland (357.013) into the insertion handle. Then fix the Hammer Guide (357.071), which is also used for nail extraction, through the protection plate firmly to the plug. Make sure the connection is very firm. Then use the Slotted Hammer (357.026) to support the insertion carefully. Remove the guide rod.

Alternative

Insertion can be supported by light hammer blows with the synthetic Hammer (399.505) directly on the protection plate mounted on the insertion handle (357.012).

Precautions:
- Avoid unnecessary use of force and only hit the hammer guide or the protection plate. Do not hit the most proximal end of the guide rod.
- If too much force is needed for insertion, the nail should be removed and the femoral shaft should be reamed again.
- It is important that the nail is always tightly connected to the insertion handle. This has to be checked especially after hammering.
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Insertion of hip pin and femoral neck screw

Please refer to the PFN standard surgical technique and choose the 125° or 130° Aiming Arm (357.015 or 357.016) for the corresponding CCD-angle of the chosen nail.

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Distal locking

Distal locking is usually performed with two locking bolts. For static interlocking position the caudal bolt at the proximal end of the locking slot, for dynamic interlocking position it at the distal end of the locking slot. If immediate dynamization is required, only use the caudal locking slot. For secondary dynamization insert both locking bolts and remove the static bolt at a later date.

Reconfirm reduction/alignment of the distal fragment.

Then use the Radiolucent Drive Mark II: Align the image intensifier with the cranial hole in the nail until a perfect circle is visible in the centre of the screen. Determine the incision point on the skin and make a stab incision.

Oblique (incorrect)  Round (correct)
Under image intensification, insert the tip of the 4.0 mm Drill Bit (511.417) into the incision and place the bit oblique to the X-ray beam until the tip is centred in the locking hole. Tilt the drive until the drill bit is in line with the beam and appears as a radio-opaque solid circle in the centre of the outer ring. The drill bit will nearly fill in the locking hole image. Hold the drill in this position and drill through both cortices. Measure the needed locking bolt length using the Depth Gauge (357.791), adding 2–4 mm to the reading to ensure thread engagement in the far cortex. Insert the bolt using the large Hexagonal Screwdriver (314.260). Repeat the procedure for the second distal locking bolt. For static interlocking place the caudal locking bolt at the proximal end of the locking slot, for dynamic interlocking at the distal end to allow dynamization.

**Note:** If the Radiolucent Drive Mark II is not available, perform distal interlocking in standard freehand technique using the 4.0 mm Drill Bit (357.068).

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**Insert End Cap**

Please refer to the PFN standard surgical technique.
1 Remove femoral neck screw and hip pin

Having made an incision through the old scar, the screws can be localized using palpation or the image intensifier. In some cases, the instruments have a better grip on the screws if a 2.8 mm Guide Wire (357.039) is inserted. First remove the end cap and insert the Hammer Guide (357.071) into the proximal nail end. Only then may the femoral neck screw, the hip pin and the locking bolt be removed by using the insertion instruments. To extract the hip pin, the Extraction Holding Sleeve for Hip Pin (357.073) is required additionally.

2 Extract nail

To remove the nail, mount the Slotted Hammer (357.026) onto the guide rod. Ensure that the guide rod is firmly seated in the nail; the 4.5 mm Pin Wrench (321.170) may be used for this purpose. Now extract the nail with slight hammer blows.

Precaution: If the soft tissue situation is difficult, the guide rod for nail extraction can be mounted after removal of all but one locking bolt in order to prevent nail rotation in the medullary cavity. Remove the last locking bolt.

Note: If the removal of the nail is not possible with the standard instruments use the special instruments from the Proximal Femoral Nail Removal Set for PFN, TFN and PFNA/PFNA-II (01.010.180) and the corresponding surgical technique (DSEM/TRM/1214/0253).
Intra-operative and postoperative cleaning

The cannulations of the instruments must be cleaned intra-operatively using the 2.8 mm Stylet for cannulated instruments (319.460) or the long 2.8 mm Cleaning Stylet (357.009, length 450 mm).

Subject to alteration.
**MRI Information**

**Torque, Displacement and Image Artifacts according to ASTM F2213-06, ASTM F2052-06e1 and ASTM F2119-07**

Non-clinical testing of worst case scenario in a 3 T MRI system did not reveal any relevant torque or displacement of the construct for an experimentally measured local spatial gradient of the magnetic field of 3.69 T/m. The largest image artifact extended approximately 169 mm from the construct when scanned using the Gradient Echo (GE). Testing was conducted on a 3 T MRI system.

**Radio-Frequency-(RF-)induced heating according to ASTM F2182-11a**

Non-clinical electromagnetic and thermal testing of worst case scenario lead to peak temperature rise of 9.5 °C with an average temperature rise of 6.6 °C (1.5 T) and a peak temperature rise of 5.9 °C (3 T) under MRI Conditions using RF Coils (whole body averaged specific absorption rate [SAR] of 2 W/kg for 6 minutes [1.5 T] and for 15 minutes [3 T]).

**Precautions:** The above mentioned test relies on non-clinical testing. The actual temperature rise in the patient will depend on a variety of factors beyond the SAR and time of RF application. Thus, it is recommended to pay particular attention to the following points:

- It is recommended to thoroughly monitor patients undergoing MR scanning for perceived temperature and/or pain sensations.
- Patients with impaired thermoregulation or temperature sensation should be excluded from MR scanning procedures.
- Generally, it is recommended to use a MR system with low field strength in the presence of conductive implants. The employed specific absorption rate (SAR) should be reduced as far as possible.
- Using the ventilation system may further contribute to reduce temperature increase in the body.